

## Other (Unclassified) (TCTAP A-001)

### TCTAP A-001

#### Twelve-month Clinical Outcomes of Transradial Coronary Artery Intervention: Comparison of the Right and Left Radial Artery Approach

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**Background:** The tranradial intervention (TRI) has several advantages such as reduction of bleeding risk, improvement of patients' convenience, and immediate ambulation as compared with the transfemoral intervention (TFI). In TRI, there are some anatomical and technical differences between right and left radial approach. The aim of this study is to evaluate the impact of the choice of the right or left radial approach on 12 months clinical outcomes in patients undergoing TRI.

**Methods:** A total of 1,653 consecutive patients underwent TRI were enrolled from Nov 2004 to Oct 2010 in Korean TRI Registry. The patients were divided into two groups; right radial approach group (n=792 pts) and left radial approach group (n=861 pts). To adjust potential confounders, propensity score matched (PSM) analysis was performed using the logistic regression model (C-statistics: 0.726). After PSM, total of 1,100 pts (550 pairs) were enrolled for this analysis.

**Results:** After PSM, the baseline clinical and angiographic characteristics were balanced between two groups. However, contrast volume during procedure were larger and fluoroscopic time ( $22.5 \pm 28.0$  min vs.  $17.1 \pm 12.6$  min) were longer in right radial approach group ( $259.3 \pm 119.6$  cc vs.  $227.0 \pm 90.7$  cc, p-value <0.001), whereas procedure time ( $49.2 \pm 30.4$  min vs.  $55.4 \pm 28.7$  min, p-value=0.003) were longer in left approach group. After PSM, procedural and in-hospital complications were similar between the two groups. The cumulative clinical outcomes up to 12 months including mortality, recurrent myocardial infarction (MI), repeat revascularization, stent thrombosis and MACE were similar between the two groups (Table).

**Conclusion:** In this study, despite the procedural efficacy including procedural time and contrast volume were increased in right artery approach, however, 12 months cumulative clinical outcomes were similar between the two groups.

Variable, N (%)	Right radial (n=550 pts)	Left radial (n=550 pts)	p Value
Mortality	21 (3.8)	26 (4.7)	0.456
Cardiac death	15 (2.7)	16 (2.9)	0.855
Recurrent Myocardial infarction	3 (0.5)	3 (0.5)	ns
Repeat Percutaneous Coronary Intervention (PCI)	25 (4.5)	27 (4.9)	0.776
Target lesion revascularization (TLR)	17 (3.0)	23 (4.1)	0.334
Target vessel revascularization (TVR)	25 (4.5)	27 (4.9)	0.776
Stent Thrombosis	5 (0.9)	0 (0.0)	0.062
MACE (Mortality, repeat PCI, MI)	44 (8.0)	53 (9.6)	0.339
MACCE (Mortality, repeat PCI, MI, CVA)	49 (8.9)	53 (9.6)	0.678

## Innovative Devices and Futuristic Therapies (TCTAP A-002)

### TCTAP A-002

#### Paclitaxel-coated Balloon Versus Paclitaxel-eluting Stent for the Treatment of Diffuse DES In-stent Restenotic Lesions: A Substudy of PEPCAD China ISR Trial

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**Background:** Treatment of drug-eluting stent in-stent restenosis (DES-ISR) is still challenging especially in diffuse lesions. The intention of this subgroup analysis is to compare the safety and effectiveness of paclitaxel-coated balloon (PCB) versus paclitaxel-eluting stent (PES) in the treatment of patients with diffuse DES-ISR.

**Methods:** PEPCAD China ISR was a prospective, multicenter, randomized (1:1), single blind trial conducted in China (n = 220). There were 33 patients in PCB (SeQuent® Please, B.Braun Melsungen AG, Germany) group and 44 patients in PES (Taxus® LibertII, Boston Scientific, Natick, MA, USA) group with diffuse in-stent restenotic lesions (Mehran type II-IV). All patients were required to undergo angiographic follow-up at 9 months and clinical follow-up at 1 month, 6 months, 1 year, and 2 years. The primary endpoint was in-segment late lumen loss (LLL) at 9 months. Secondary endpoints included % diameter stenosis (DS), binary restenosis rate, and target lesion failure (TLF), a composite of cardiac death, target vessel myocardial infarction (MI) or ischemia-driven target lesion revascularization. In addition, definite/probable stent thrombosis (ST) rates were documented.

**Results:** There were no significant baseline differences between both treatment groups in terms of patient, lesion or procedural characteristics. At 9 months, in-segment LLL in the PCB group was comparable to the PES group ( $0.74 \pm 0.53$  mm vs.  $0.80 \pm 0.74$  mm, p = 0.69). The rates of 9-month in-segment binary restenosis, 12-month TLF, composite of all cause death, all MI and any revascularization, and definite/probable ST were no statistical differences between both treatment groups (27.3% vs. 32.4%, p = 0.65; 21.2% vs. 15.9%, p = 0.55; 27.3% vs. 29.5%, p = 0.83; 3.0% vs. 0.0%, p = 0.43, respectively).

**Conclusion:** The present substudy offers preliminary evidence that DES-ISR patients with diffuse lesions receiving PCB therapy were non-inferior to PES implantations. However, current treatment options with either PES or PCB are not optimal for diffuse in-stent restenotic lesions after DES failure. Further innovative therapies are needed to address this kind of particularly difficult patients. (ClinicalTrials.gov identifier: NCT 01622075).

## Valvular Heart Disease (TCTAP A-003)

### TCTAP A-003

#### Comparison of Multi-detector Row CT Morphology Between CoreValve and Edwards Sapien Valve After Transcatheter Aortic Valve Implantation

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**Background:** This study sought to compare the morphological characteristics and underlying mechanism of paravalvular leak (PVL) after transcatheter aortic valve implantation (TAVI) using the CoreValve (Medtronic, Santa Rosa, California) and the Edwards valve (Edwards Lifesciences, Irvine, California).

**Methods:** A total of 68 TAVI patients (aged  $84.2 \pm 7.4$  years, Logistic EuroSCORE  $21.5 \pm 12.4$ ) who had pre and post-procedural multidetector computed tomography (MDCT) were studied.

**Results:** In this cohort, 43 (63.2%) patients were treated with the CoreValve and the remaining 25 (36.8%) patients received the Edwards valve. Post-TAVI eccentricity index was significantly higher in patients of the CoreValve group at each level of prosthesis (stent bottom  $18.4 \pm 9.23$  vs  $5.2 \pm 4.0$ , p < 0.01, annulus level,  $19.0 \pm 8.9$  vs  $5.8 \pm 7.8$ , p < 0.01, leaflet level  $16.6 \pm 8.3$  vs  $4.5 \pm 3.5$ , p < 0.01). By multivariate analysis, only the Valve Calcification Index (aortic valve calcification volume/body surface area) was identified as independent predictor of any post-procedural PVL after CoreValve implantation (odds ratio [OR] 1.002, 95% confidence interval [CI] 1.000-1.004, p=0.03). In patients with Edwards valve, post-TAVI eccentricity index (leaflet level) was identified as an independent predictor of post-procedural PVL (OR 1.31, 95% CI 1.02-1.68, p=0.04).

**Conclusion:** Post-TAVI valve eccentricity was more frequently observed in CoreValve implantation than after Edwards valve implantation. Valve eccentricity was associated with PVL after Edwards valve implantation but not after CoreValve implantation probably because of the supra-annular design of the CoreValve.